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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,704

12/12/2005

Richard James Lewis

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EXAMINER

AUDET, MAURY A

ART UNIT

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1654

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/537,704	Applicant(s) LEWIS ET AL.	
	Examiner Maury Audet	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 & 6-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**Detailed action**

**The present Application has been transferred from former Examiner Young to the present Examiner.**

**There are not new claimed amendments. Applicant's response of 6/22/07 is acknowledged. For continuity of record, the relevant sections of the previous action have been kept herein. This Examiner's responses to Applicant's traversals/inquires are provided in bold under each relevant section below, for clarity.**

***Restriction election and traversal acknowledged***

**The FINAL restriction requirement is maintained as provided previously.**

1. Applicant's election with traverse of Group I, claims 1-7, and the species election of SEQ ID NO: 4, in the reply filed on December 4, 2006 is acknowledged. The traversal is on the ground(s) that the claims have unity of invention under PCT Rule 13.1. This is not found persuasive because it is proper to rely on evaluation of novelty or unobviousness when making a determination of unity of invention, the unity of invention of the instant application's claim set being broken by the prior art cited by the Examiner, Balaji et al. (*J. Biol. Chem.* 275(50):39516-22, 2000) does teach the special technical feature of the instant claims, the structure of the chi-conotoxins. In regards the linking claim 8 recited in Applicant's response on page 4, it is drawn to non-elected inventions II-VII. Claim 5 is withdrawn as being drawn to non-elected species, the elected species being found unpatentable (see below).

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1-4 and 6-7 over McIntosh et al. in view of Jones et al. is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. At the outset, it is noted that Applicant suggests the previous Examiner should have made the 103 rejection under the combination of McIntosh et al. in view of Jones et al. – both drawn to modified conotoxin peptides, just like the present invention. Substantively, it appears the previous Examiner intended this to be a combination rejection and for clarity this Examiner has so amended the rejection. However, the present Examiner also notes, that based on the limited number of options (3) in the Markush group of McIntosh et al., as to what may constitute position 1 of the conotoxin peptide of McIntosh et al., that the primary reference alone carries enough weight based on the specificity of options, that a single reference 103 over McIntosh et al. could have been reasonably made.

As to the modified conotoxin peptide formula of McIntosh et al., the native conotoxin peptide options are fixed as the first option of each Xaa option of the formula. And specifically, as to Xaa1 (Asn, Gln, pGlu) and Xaa6 (Pro, hydroxy-Pro (e.g. 4-hydroxyproline) or g-Hyp) – there are ONLY three amino acid options thereto, one of which is the native amino acid. As to the latter, hydroxyl-Pro is a

known modified amino acid version of Pro. It is the Xaa1 position that is primarily at issue here and discussed in detail below.

Thus, the issue presented is whether one of ordinary skill in the art at the time of the invention would have been motivated by the teachings/suggestions of McIntosh et al. alone or in view of Jones et al. to select pGlu in position 1 of same conotoxin peptide (over native Asn) of McIntosh et al. (e.g. elected species of presently claimed SEQ ID NO: 4), from a Markush group of ONLY three amino acid options (Asn, Gln, pGlu) – 1 of which, Asn, is the native amino acid? In this regard, and as to the substantive teachings/suggestions/motivations outlined by the previous Examiner as to both references, this Examiner maintains the rejection for the reasons of record.

In fact, this Examiner believes that since only three options were presented in McIntosh et al. as to the position 1 Markush group: Asn, Gln or pyro-Glu; that one of ordinary skill in the art, based on the limited number of options presented, would have routinely used any of the three options in the invention. Were McIntosh to have presented an actual laundry list or options for position 1 (e.g. > 5, 8, 10 amino acid options), it may be arguable that there would be not motivation to select any specific one, akin to rising to the level of written description as to which of said options McIntosh was really in “possession” of. However, as only three distinct options were present, such is not the case here – and import of ‘why one would choose pGlu from this Markush group is really misplaced. There are 3 options here. Period. McIntosh intended these 3 options

to used in position 1. If Applicant has found an unexpected result using 1 of the 3 options, such an argument does not remove the fact that McIntosh et al. had possession of the 3 options, one which is pGlu, at position 1, of his conotoxin peptide.

It appears the previous Examiner wished to substantively back this up by showing that pGlu was also known to be used in other conotoxin peptides (e.g. Jones et al.). Whether Jones et al. substituted pGlu for a different purpose, as Applicant alleges, does not change the present Examiner's position that the previous Examiner properly used the Jones et al. reference to show that pGlu was a known, selected substitution, in conotoxin peptides. Jones et al. merely further provides evidence of selection (not hindsight or any sense of "teaching away") - that one of ordinary skill in the art, at the time of invention, would have selected pGlu in position 1, in McIntosh et al. Alternatively, one of the other two choices of McIntosh et al. could have been selected (Asn or Gln). Again, were this to have been a true laundry list, the present Examiner may agree with Applicant's arguments that Jones et al. does not provide the teaching/suggestion/motivation to specifically select pGlu. However, from a group with a mere 3 specific options, this argument is not deemed to presently carry the day on this issue, either over McIntosh et al. alone OR McIntosh et al. in view of Jones et al.

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2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntosh et al. (US Patent 6,767,896 B1, issued July 27, 2004, filed as application No: 09/580,201 on May 26, 2000), in view of Jones et al. (US Patent Application Publication 2005/0271589 A1, published Dec. 8, 2005).

McIntosh et al. describe and claim conotoxin peptides in. McIntosh claim a conotoxin peptide in their Claim 1, recited as a Markush group of as many as 14 amino acids, with the C-terminal residue as possibly absent. The recited members of the Markush group of possible amino acid residues include all of those claimed in Lewis et al's instant SEQ ID NO: 4, specifically pGlu-GVCCGYKLCH-Hyp-C. It is obvious to select members of a known Markush group for use in or as specific embodiments or species of the genus described by the Markush group. The selection of the second amino acid through to the penultimate amino acid are further impelled by the fact that they correspond to the natural product, chi-Mrl, A or B, as disclosed in the instant Specification as SEQ ID NOS: 1 and 2, respectively, on page 2, lines 4 and 5. The penultimate residue, the modified 4-hydroxyproline is itself a natural, post-translational modification as disclosed by applicant in lines 7-9, page 2 of the Specification. The use of or substitution with pyro-glutamate at the N-terminal end of a conotoxin sequence is similarly discussed by Jones et al, in US Patent Application Publication 2005/0271589

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A1, published Dec. 8, 2005. Jones et al. indicate in paragraph [0014], page 2, that the N-terminal Glutamine can be substituted with pyro-Glutamate, designated (Z) in the one-letter sequence codes. They also claim this use of pyro-Glutamate in their claims 1, 2, 24, 29 and 34 (in the Claims). It is interesting to note that the use of an N-terminal pyro-glutamate appears to provide an obvious advantage in that Jones et al. describe conotoxin peptide sequences from more than one species of the genus *Conus* (*C. miles*, *tulipa*, *sulcata*, *purpurascens*, and *geographicus*) to which N-terminal pyro-glutamates are attached or substituted regardless of the differences these conotoxins have in regards the remainder of the peptide sequences. Jones et al. similarly state these common substitutions of conotoxin amino acids in US Patent Application Publications 2004/0176278 and 2003/0170222.

***Double patenting rejection***

**The rejection is maintained for the reasons of record. The '088 application has the same priority date as the present application, and remains under examination on the merits as to one or more overlapping peptides (e.g. SEQ ID NO: 5). At such time as the present application be found to contain allowable subject matter, a Terminal Disclaimer will be required should the overlapping subject matter remain.**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims



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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 5, 6, 12, 13, 15-21, 38-41, 43, 45, 47, and 49 of copending Application No. 10/537,088. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of conotoxin peptide claimed in the instant 10/537,704 as the elected peptide species SEQ ID NO: 4 is part of the Markush group comprising the conotoxin peptides claimed in the copending 10/537,088 as SEQ ID NO: 4 (in copending claim 2) and SEQ ID NO: 5 (in copending claims 5 and 6). Claims depending from the copending claims 2, 5 and 6 are directed towards further narrowing the Markush group, rendering the instant SEQ ID NO: 4 of 10/537,704 as a species of an ever smaller genus. The peptide sequence SEQ ID NO: 3 (instant claims 1 and 2), which is the foundation of the instant claim set in 10/537,704 is similarly within the bounds of the SEQ ID NO: 4 of the copending 10/537,088.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Objections to the claims***

As to Applicant's question regarding the confusion of the previous Examiner's Objection to the claims (see below), as the previous Examiner is no longer Examining, the present Examiner was not able to confer with him. However, based upon a reading the below, it is assumed a search of SEQ ID NOS: 10 and 11 were undertaken, and found to not be reasonably taught or suggested by the prior art of record. As these claims are not the elected species, they have not been Examined on the merits, thus the below was provided as a courtesy to Applicant as to the results which were uncovered as to the below, for Applicant to consider his is strategy on the application.

6. Claims 5, 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 5 is drawn to SEQ ID NOS: 10 and 11, rather than the elected species of SEQ ID NO: 4, and was not considered on its merits in this action, other than to note that it is drawn to a rejected independent claim, claim 1.

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**Conclusion**

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAA, 10/28/07

  
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